The Examiner has rejected Claims 7-12 and 17-23 under 35 U.S.C. 102(a) as being anticipated by Wagner et al. (WO 97/49394). The Applicants respectfully disagree with the Examiner and request that the Examiner withdraw the rejections dependent thereon.

In order for a rejection under 35 U.S.C. 102(a) to be proper, every limitation in applicants' claims must be identically described by Wagner. Wagner et al. claim in independent claim 12 in combination with the dependent claim 14, a composition which has a microcrystalline cellulose concentration of less than 30% microcrystalline cellulose. Wagner et al. generally disclose that microcrystalline cellulose may be used in the composition of that invention. However, Wagner, et al., provide specific disclosure of the appropriate quantities of microcrystalline cellulose to be between below 30% for their claimed solid oral dosage of valsartan or a composition which contains *both* valsartan and hydrochlorothiazide (HCTZ) as the active ingredients (see page 7 lines 5 through 18). Additionally, Wagner et al. do not disclose that their composition actually approximates the bioavailability or dissolution of a capsule form of valsartan, which was the marketed form of valsartan at the time of the disclosure of Wagner et al.

The Applicants have selected a novel concentration range for microcrystalline cellulose of between 30% to 65% because they have unexpectedly determined that this concentration of microcrystalline cellulose affords a tablet dissolution and associated bioavailability which is within accepted dissolution standards for the then marketed *capsule form* of valsartan known as DIOVAN ® tablets of the single active agent valsartan (see page 26 lines 23 – 26 of Applicants' disclosure and Examples 1 through 11 and also Example 12 on page 37 of the applicants' disclosure). The Applicants' particular selection of 30% to 65% of microcrystalline cellulose based on their finding and the associated claims of the Applicants are novel and are not disclosed by Wagner et al. The Applicants thus respectfully disagree with the Examiner and request that the rejection under 35 USC §102 (a) based thereon be withdrawn.

The Examiner has rejected Claims 13 and 24 under 35 U.S.C. 103(a) as being unpatentable over Wagner et al. (WO 97/49394) in view of Pool et al. (1998). The Applicants respectfully disagree and request that the Examiner withdraw the rejection of claims dependent thereon.

The Applicants' specification, as originally filed, on page 24, lines 13-15, after exhaustive testing, applicants determined that increasing the amount of microcrystalline cellulose to greater than 30%, improves the bioavailability of solid formulations. While Wagner, et al. describe a range for binders, Wagner clearly teaches in the examples that when the binder is microcrystalline cellulose, the amount of binder required is between less than 30% and specifically 21%. Thus, the required amount of microcrystalline cellulose taught by Wagner does not overlap with the amount required by Applicants.

Pool describes treating patients with valsartan in doses of 10, 20, 40, 80, 160, and 320 mg once daily. However, Pool fails to teach or suggest any other ingredients other than valsartan.

Thus, combining the teachings of Wagner and Pool would not lead one skilled in the art to increase the amount of microcrystalline cellulose to between 30 and 65%, in order to increase the bioavailability of valsartan formulations, as claimed by Applicants.

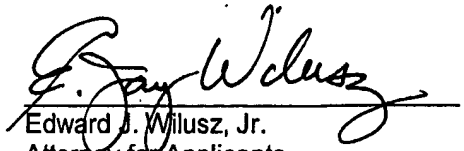
The Applicants claims for varying amounts of inactive ingredients in the composition of the invention depend from the novel and unobvious composition claimed in claim 8. Thus the claimed composition of valsartan with a microcrystalline cellulose composition of from 30 to 65% is itself novel and unobvious, and any additional inactive ingredients added to the compsotion of claim 8 as it now stands are also novel and unobvious. Therefore claim 24 is unobvious over Wagner and Pool.

Applicants respectfully request that the rejection of the claims under 35 U.S.C. §102(a) and 103(a) be withdrawn. Applicants believe that pending claims 8-14 and 17-24 are allowable and request early notice to that effect.

It is believed that no further fees are due in this application. However if additional fees are properly assessed, the Examiner and USPTO are authorized to charge Deposit Account No. 19-0134 in the name of Novartis Corporation for the fee required under 37 C.F.R. § 1.17(a) or to refund any overpayment to same account.

If it will forward prosecution of the application the Examiner is urged to telephone the Applicants' undersigned counsel at the number listed below.

Respectfully submitted,



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Date: 12 January, 2004

Amended Claims:

Claim 7 (deleted): ~~A solid oral dosage form comprising valsartan in free form and more than 30% of microcrystalline cellulose by weight based on the total weight of the core components of said form.~~

Claim 8 (amended): A solid oral dosage form according to claim 7 comprising valsartan in free form and more than 30% up to 65% of microcrystalline cellulose by weight based on the total weight of the core components of said form.

Claim 9 (amended twice): A solid oral dosage from according to claim ~~7~~ 8 comprising less than 13% of crospovidone.

Claim 11 (amended twice): A solid oral dosage form according to claim ~~7~~ 8comprising 20 to 65% of valsartan.

Claim 12 (amended twice) A solid oral dosage form according to claim ~~7~~ 8 comprising 20 to 360 mg. of valsartan.